



# UNITED STATES PATENT AND TRADEMARK OFFICE

*ck*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/826,119

04/16/2004

Toyoko Kusama

NANP119US

1349

7590

01/08/2007

Gregory Turocy  
Amin & Turocy, LLP  
24th Floor, National City Center  
1900 East 9th Street  
Cleveland, OH 44114

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

01/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/826,119

Applicant(s)

KUSAMA ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,26-34,36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,25 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/28/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election of Group II (claims 22-33, 35-36), in the reply filed on November 09, 2006 is acknowledged. The response neither provides any indication whether the election is with traverse or without traverse nor provided arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

With regard to the election of a pair of primer sequences for examination, Applicants' arguments are fully considered and found persuasive in part. The search for additional pair of sequences (SEQ ID No. 3 and 4) would be considered in this office action. However as discussed in the previous office action each pair of primers amplify a different variant which comprises a polymorphism or mutation which results in a structurally different nucleic acid thus the restriction to the SEQ. ID. is deemed proper. With regard to the species election, Applicants' arguments are found persuasive in part and the restriction to the species (a)-(d) is withdrawn herein in view of the persuasive arguments. However the restriction to the species (h)-(m) are maintained herein.

***Status***

2. Claims 24-25, 35 (in part) read on elected pair of sequences and elected species and are considered for examination. Claims 1-23, 26-34, 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

***Information Disclosure Statement***

3. The Information Disclosure Statement filed on July 28, 2004 has been entered and considered in part. The JP document is in foreign language and is not considered since Applicants did not provide a copy of translation to the document.

***Priority***

4. This application is filed on April 16, 2004.

***Objection to the abstract of the disclosure***

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because abstract contains the form and legal phraseology, that is, 'said method' in the 2<sup>nd</sup> line of the abstract. Correction is required. See MPEP § 608.01(b).

***Objection to the Drawings***

6. The Drawings is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Figure 1 -4) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-25, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saulle et al. (J Animal Sciences, Vol. 77, pp. 3398-3399, 1999) in view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990).

Saulle et al. teach a nucleic acid sequence of ATPase8 mitochondrial gene of claims 24 and 35, comprising primer sequences of SEQ ID No. 3-6 as claimed (see page 3398, col.1, paragraph 5, Accession number AF104682, and also see sequence alignment from GenEmbl. database).

With regard to claim 25 Saulle et al. teach that said nucleic acid is of a ruminant deer (alpine ibex) (see page 3398, col. 1, paragraph 5).

However did not teach the combination of primers or primer pairs.

Lowe et al. teach a method for designing primers and evaluating their performance wherein Lowe et al. disclose a computer program for rapid selection of oligonucleotide primers for polymerase chain reaction (see page 1757, col. 1, abstract). Lowe et al. teach that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe (see page 1760, col. 2, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the known nucleic acid sequence as taught by Saulle et al. with a step of generate primers and designing primers as taught by Lowe et al. to amplify and increase the primer specificity and to detect a ruminant-specific DNA because the ATPase8 mitochondrial gene sequence is known (as taught by Saulle et al.) to an ordinary skill in the art at the time the invention was made, and it is obvious to generate primers from the known sequences as taught by Lowe et al. The ordinary artisan would have had a reasonable expectation of success that such primers or primer pairs generated using known sequences as taught by Saulle et al. in view of Lowe et al. to amplify a ruminant-specific DNA for detection because the claimed primers are functional equivalents of the sequences taught by Saulle et al. and Lowe et al. explicitly taught that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size (see page 1760, col. 2, paragraph 1). The ordinary artisan would have been

motivated to generate a number of said primers and primer pairs for detection of ruminant-specific DNA, such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs. Further, selection of specific oligonucleotides for specific  $T_m$  represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Lowe et al. (This clearly shows that every primer would have a reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe or primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

#### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/826,119  
Art Unit: 1637

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru  
Primary Examiner  
Art Unit 1637

  
SURYAPRABHA CHUNDURU 1/3/07  
PRIMARY EXAMINER